English speaker; 4) comparison of original and back translation; and 5) review by a clinician. **RESULTS:** Cultural and linguistic challenges emerged during the process. On the cultural level, the differences in the approach to suicide and its methods based on differences in tradition and availability of means required finding suitable alternatives in the target languages. On the linguistic level, it was important to differentiate between medical and psychiatric hospitalisation after a suicide attempt and appropriate solutions across languages had to be found. The process revealed an area of ambiguity in the original rating instructions which had to be clarified in the translations. Examples of these and other challenges and their solutions will be discussed in the presentation. **CONCLUSIONS:** The 45 language versions, of the C-SSRS (a total of over 90 translations now exist), were established according to a rigorous methodology to ensure conceptual equivalence and cultural relevance across languages. The translations may now be used in international studies to assess suicidal ideation and behaviour and facilitate the comparison and pooling of data. The analysis of the psychometric results will be necessary to see if and how suicidal ideation and behaviour compare across countries and cultures.

QL3

ACCESS TO HEALTH-RELATED QUALITY OF LIFE (HRQL) INSTRUMENTS AND THEIR TRANSLATIONS IN THE LIGHT OF EMEA RECOMMENDATIONS

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INTRODUCTION: The EMEA reflection paper on HRQL specifies that the claim in the Summary of Product Characteristics (SmPC) with respect to HRQL will always be considered depending on the strength of the evidence, which should be based on 6 criteria, amongst these are the justification of the choice of the HRQL instrument(s), and the evidence of validation (including for translation). To meet these requirements, users should have access to reliable and updated information. To determine if these can be met, it is necessary to review how users access information about HRQL instruments. **OBJECTIVES:** 1) To investigate how developers organize the release of information about their instrument; 2) to comment on the pros and cons for each identified dissemination strategy; 3) To make recommendations for instrument developers to facilitate users' access to information. **METHODS:** we conducted a review of the 2,850 information requests addressed to our Information Resources Centre in 2007. The requests were categorized according to the type of information needed: 1) information about the original instrument; 2) conditions of access/use of instruments/translations; 3) validity of instruments/translations; 4) translation certification; 5) intellectual property. To address these, we made 900 contacts with developers, translators, publishers and other licensing authorities. **RESULTS:** Out of the dissemination strategies identified and reviewed, five trends emerged between two extremes: 1) uncontrolled, de-centralized, free access to non-updated information without developer's input; 2) controlled, copyright-protected, centralized, fee-paying access to reliable and updated information with developer's input. Advantages and disadvantages of strategies will be discussed. Examples demonstrate that the controlled strategy is more compliant with the EMEA evidence requirements. **CONCLUSION:** Findings indicate that how a user can comply or not with the EMEA requirements is directly related to how developers organize the release of information about their questionnaire and translations. Promoting a controlled, centralized system with developers' input may facilitate access to reliable and updated information.

QL4

PREDICTING EQ-5D, SF-6D AND 15D UTILITIES FROM EORTC QLQ-C30 DATA

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OBJECTIVES: To determine if the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) can satisfactorily predict EQ-5D, SF-6D and 15D utilities. The QLQ-C30 measures health-related quality of life (HRQOL) using a global scale, five functional scales and eight symptom scales/items and like most HRQOL instruments provides a profile of scores instead of an overall preference-based index, precluding its use in cost-utility studies. **METHODS:** A stratified sample (N = 48) of gastrointestinal cancer patients on chemotherapy was interviewed. The survey contained the QLQ-C30, the SF-36, two multi-attribute utility instruments (EQ-5D and 15D) and socio-demographic and disease-related questions. Validity of QLQ-C30 scales was assessed by testing a priori hypotheses that they would be moderately or strongly correlated with SF-36 scales measuring similar HRQOL dimensions and that younger subjects and those not reporting comorbid conditions would have better scores. Linear regression analyses identified the extent to which QLQ-C30 scales could predict EQ-5D, SF-6D and 15D utilities. **RESULTS:** Pearson's correlations between similar QLQ-C30 and SF-36 scales ranged from 0.69 to 0.89 ($P < 0.001$). Subjects with coronary heart disease had worse scores on all QLQ-C30 functional scales (T-test, $P < 0.05$ for four scales), as did older subjects as well (ANOVA, $P < 0.05$ for five scales). QLQ-C30 global, functional and symptom scales were significant predictors of utility scores elicited from standard instruments. Specifically, three scales were significant ($P < 0.05$) predictors of EQ-5D utilities, six scales ($P < 0.05$) of SF-6D utilities and four scales ($P < 0.001$) of 15D utilities and explained large portions of variance (adjusted R^2 was 0.610, 0.833 and 0.912 respectively). Robustness of results was tested and confirmed in patient subgroups with differing HRQOL. **CONCLUSIONS:** Preliminary evidence has been provided supporting the appropriateness mainly of the 15D and SF-6D instruments in cancer-specific cost-utility studies, although further studies involving larger and more diverse patient samples are encouraged.

PODIUM SESSION II: CARDIOVASCULAR DISEASE EVALUATIONS

CV1

WHAT IS THE CLINICAL BENEFIT OF PREVENTING NON-FATAL MYOCARDIAL INFARCTIONS?

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OBJECTIVES: Therapies may reduce short-term rates of non-fatal myocardial infarction (MI) while having no detectable effect on in-trial mortality. We sought to estimate the clinical benefit of preventing a non-fatal MI in terms of its effects upon long-term rates of death and MI. **METHODS:** We analyzed 14,890 patients with significant coronary artery disease (CAD) undergoing diagnostic catheterization (cath) at Duke Medical Center between 1999 and 2006, with follow-up through June 2007. Patients were classified as having a non-fatal MI within three months of

their index cath (MI Group) or as being event-free at three months (No MI Group). Outcomes through four years were assessed in landmark analyses using Cox proportional hazards techniques. **RESULTS:** Patients in the MI vs. No MI Groups had a median of 4.2 years follow-up and were similar in age (62 vs. 63 years, p = .44), female sex (35% vs. 33%, p = .35), history of hypertension (69% vs. 68%, p = .77), history of diabetes (35% vs. 30%, p = .08), and in multi-vessel CAD (61% vs. 58%, p = .17). At four years follow-up, patients in the MI vs. No MI Groups had higher unadjusted rates of death (25% vs. 17%, p < .001) and death or MI (34% vs. 21%, p < .001). After adjustment, the hazards of death for patients in the MI vs. No-MI Groups (HR 1.62; 95% CI 1.30, 2.02; p < .001) and death or MI (HR 1.84; 95% CI 1.51, 2.24, p < .001) remained significant. When we extended the landmark period from three to six months after the index cath, the adjusted hazards of death (HR 1.61; 95% CI 1.34, 1.93; p < .001) and death or MI (HR 1.86; 95% CI 1.58, 2.19; p < .001) were still significant. **CONCLUSIONS:** Non-fatal myocardial infarctions significantly increase subsequent rates of death and death or MI in CAD patients. These findings suggest a long-term clinical benefit for therapies that avert non-fatal MIs.

CV2

A NEW MEASURE FOR ASSESSING HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN PATIENTS WITH ATRIAL FIBRILLATION: AF-QOL

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OBJECTIVES: To assess AF-QoL questionnaire performance in patients with Atrial Fibrillation (AF) in a usual clinical practice setting. **METHODS:** Observational, prospective, multicenter study was carried out in 29 Spanish centres. AF diagnosed patients aged ≥18 who have changed a clinical and/or therapeutic intervention or were stable according to clinical criteria, and patients with post heart attack cardiopathy (control group) were enrolled. All patients went through a baseline visit; only AF patients underwent a follow up visit (at 3 ± 1 months and 1 month for unstable and stable patients respectively). At each visit, socio-demographical and clinical information was gathered; AF-QoL, SF-36 questionnaires and perception of general health status were administered. AF-QoL is an 18-item questionnaire with 3 domains: psychological, physical and sexual. Questions refer to previous month. Answers are 5 levels Likert-like. AF-QoL scores range between 0–100, where 0 is poor HRQoL. **RESULTS:** A total of 417 patients were included: 341 AF patients and 76 control patients. Mean (SD) age was 61.2(12.4) and 31.4% were women. AF type distribution was: 37.5% paroxysmal, 42.9% persistent and 19.6% permanent. AF-QoL was completed by 88.5% of patients. AF-QoL mean overall global score in AF patients was 43.6 and 51.7 in control group (p < 0.05). AF-QoL showed good internal consistency (0.92) and good test-retest reliability (0.86) in stable AF patients. Patients with more symptoms and worse NYHA functional class at baseline and at the end of follow-up visit showed lower scores in AF-QoL. AF-QoL correlations with SF-36 and overall perception of general health status question were moderate-high (0.32–0.69) and moderate (0.49) (p < 0.01) repectively. AF-QoL effect size scores in patients declaring health status positive changes was 1.06, 0.2 for those with no changes and 0.1 for patients with negative changes. **CONCLUSIONS:** AF-Qol has shown to be feasible, valid, reliable and responsive to clinical changes in the context of clinical practice.

CV3

PREDICTED OPTIMAL LIPID VALUE ATTAINMENT WITH THE CO-ADMINISTRATION OF FENOFIBRIC ACID AND A STATIN COMPARED TO STATIN MONOTHERAPY IN PATIENTS WITH MULTIPLE LIPID ABNORMALITIES

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OBJECTIVES: To predict the percentage of patients achieving multiple optimal lipid values (OLV) after one year of combination fenofibric acid (FA) + statin therapy or statin monotherapy. **METHODS:** A dyslipidemia outcomes model was used to predict multiple OLV attainment (any 3 of 4 targets: total-C, LDL-C, HDL-C, or TG) among a cohort of 1000 patients with multiple lipid abnormalities (MLA). Optimal lipid levels for HDL-C (value >40 mg/dL for men, >50 mg/dL for women), LDL-C (value <130 mg/dL), TG (value <150 mg/dL), and total-C (value <210 mg/dL) were based on U.S. clinical practice guidelines. Baseline lipid values were simulated with National Health and Nutrition Examination Survey data, used to determine the shape of lipid distributions (gamma for TG and log normal for the others) and the correlation between these parameters. Mean initial and on-treatment lipid values were obtained from three 12-week FA/statin studies, where FA 135 mg co-administered with atorvastatin, rosuvastatin, and simvastatin at low (20 mg, 10 mg, 20 mg, respectively) and moderate doses (40 mg, 20 mg, 40 mg, respectively) was compared to FA and corresponding statin monotherapy doses. **RESULTS:** Compared to equivalent statin monotherapy, the addition of FA 135 mg to low-dose simvastatin, rosuvastatin, and atorvastatin was predicted to result in 43% (678 vs. 473 per 1000), 31% (814 vs. 621 per 1000), and 43% (723 vs. 506 per 1\000) more patients simultaneously achieving multiple OLV. The number of patients predicted to achieve multiple OLV increased by 16%, 18% and 25% with FA + moderate-dose simvastatin, rosuvastatin, and atorvastatin over equivalent dose statin monotherapy, respectively. **CONCLUSIONS:** Patients with MLA receiving statin monotherapy may require add-on treatment to achieve multiple lipid targets. This analysis suggests that treatment with FA in combination with low- and moderate-dose statin therapy may enable more patients to simultaneously achieve OLV compared to statin monotherapy.

CV4

COST-EFFECTIVENESS ANALYSIS OF IVABRADINE IN STABLE ANGINA PATIENTS IN THE NETHERLANDS

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OBJECTIVES: To assess the cost-effectiveness of ivabradine in stable angina patients in the Dutch health care setting in 2007. **METHODS:** A Markov model was developed to estimate the cost-effectiveness of ivabradine. The analysis was performed for stable angina patients, who currently are candidate for revascularisation. Data sources used included 1) Ivabradine clinical trial data, 2) Data of the Dutch Heart Foundation, and 3) Data of the Euro Heart Survey (European Cardiology database). Furthermore, published literature, official Dutch price/tariff lists and national population statistics are used. The time horizon of the model was 5 years in order to capture the long-term economic impact of ivabradine. **RESULTS:** The results show that the use of ivabradine leads to additional drug costs of €3873 over a period of 5 years, which are offset by a cost saving of €8699 due to fewer revascularisations (€1210 in the ivabradine arm versus €9909 in the revascularisation arm) over a period of 5 years. As a result the